

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application are respectfully requested.

In the RCE filed herewith, Applicants have requested entry of the Reply and Amendment dated May 30, 2002. The Advisory Action dated June 11, 2002 stated that the proposed amendments would not be entered because they raise new issues and the issue of new matter. The Advisory Action states that the exclusion of γ -linolenic acid from some of the claims raised new issues. Nothing is specified regarding how the amendment raised the issue of new matter. This issue thus cannot be addressed herein. No new matter was believed to have been introduced by the prior amendment.

In the instant amendment, new claims 51-56 have been added. These claims specify that the unsaturated fatty acids are arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid. Arachidonic acid is specified in dependent claims 52 and 55. In claims 53 and 56, the microorganism is said to be *Mortierella exigua* or *Mortierella hygrophila*. Support for these claims may be found at the very least in the original claims and at page 5, lines 1-7 and 35-37. No new matter has been added.

The claims stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Suzuki et al taken with Manoh et al and Yamaguchi et al. The new claims added by this amendment are patentably distinguishable from the cited art.

Suzuki et al discloses a process for producing γ -linolenic acid in a medium. First, Suzuki et al does not disclose the production of arachidonic acid, dihomo- γ -linolenic acid,

5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid, as specified in claims 51-56.

Similarly, Manoh et al does not disclose the production of arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid. Manoh, like Suzuki et al, only discloses the production of γ -linolenic acid. Yamaguchi et al is also unrelated to the production of arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid. Yamaguchi et al instead teaches a method for producing (-) trans-2,3-epoxysuccinic acid, which compound is not even an unsaturated fatty acid.

The combination of references thus fails to disclose or even suggest a process for producing unsaturated fatty acids selected from the group consisting of arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid, or a lipid containing them, as claimed. Nor is there any motivation in the art to apply the teachings regarding the production of γ -linolenic acid to a method for producing the claimed unsaturated fatty acids.

Moreover, there is no motivation to combine Suzuki et al, Manoh et al and Yamaguchi et al together as proposed. Suzuki et al and Manoh et al are both directed to the production of γ -linolenic acid. Yamaguchi et al is directed to the production of (-) trans-2,3-epoxysuccinic acid. There is nothing to suggest that conditions used for production of (-) trans-2,3-epoxysuccinic acid should be applied to processes for production of γ -linolenic acid. Nor is there any suggestion to make the next leap in the rejection, as it applies to the new claims, that these teachings are relevant in a process for producing arachidonic acid, dihomo- γ -linolenic acid, 5,8,11-eicosatrienoic acid and/or eicosapentaenoic acid.

Furthermore, none of the cited art is directed to the use of microorganism from the genus *Mortierella*, wherein the microorganism is selected from the group consisting of *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hygrophila*. Suzuki et al discloses the use of *Mortierella isabellina*, *Mortierella vinacea*, *Mortierella rammaniana*, *Mortierella ramanniana* var. *Angulispora*, and *Mortierella nana*. Suzuki et al does not disclose the use of *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hydrophila*, as claimed. The *Mortierella* of Suzuki et al are members of the subgenus *Micromucor*, while those of applicants' invention are of the subgenus *Mortierella*. One skilled in the art would recognize that the Suzuki et al microorganisms are distinct from those of the instant claims, for example, the *Micromucor* cannot produce unsaturated fatty acids having more than 18 carbon atoms, while *Mortierella* can. See, Amano et al, *Mycotaxon* 44(2):257-65 (1992), previously submitted.

Manoh et al uses a microorganism from the genus *Cunninghamella* to produce γ -linolenic acid. There is nothing to suggest that conditions relating to culturing of *Cunninghamella* would be useful for culturing *Mortierella*. Nor does Yamaguchi et al teach a process for production using a microorganism from the genus *Mortierella*. Yamaguchi et al is instead directed to culturing *Aspergillus clavatus*.

Since the references all employ different microorganisms, there is no reason for one skilled in the art to combine the references as proposed. Moreover, since they are unrelated to the claimed microorganism, there is no suggestion that the teachings of the references should be applied to a production process wherein the microorganism is selected

from the group consisting of *Mortierella alpina*, *Mortierella elongata*, *Mortierella exigua* or *Mortierella hygrophila*.

Furthermore, Manoh et al does not disclose or suggest a preferred calcium concentration in its culture medium. In Example 3, 20 mg/l of Calcium chloride is used. This figures out to .26 mM of calcium, which is significantly less than the 0.5 to 12 mM of calcium used in the culture medium of the present invention. Therefore, Manoh et al does not disclose or suggest the claimed invention, even if taken together with Suzuki et al.

Applicants unexpectedly found that by adding the ions as claimed to the culture medium, beneficial results in terms of production were achieved. This is shown for the microorganisms and fatty acids recited in new claims 51-56. In Examples 1-3, a *Mortierella alpina* was used and an increase in the production of arachidonic acid was found. In Example 4, *Mortierella elongata*, *Mortierella exigua* and *Mortierella hygrophila* were used to produce arachidonic acid. *Mortierella alpina* was used in Example 5 to produce arachidonic acid. Example 6 shows an increase in production of Mead acid and dihomo- γ -linolenic acid by the claimed addition of ions using a *Mortierella alpina* microorganism. These increases in production would not have been expected prior to the instant invention. Unexpected and beneficial results are thus achieved by applicants' claimed invention.

Therefore, in light of the above, at the very least, the rejection under 35 U.S.C. § 103(a) would not apply to new claims 51-56 added by this amendment.

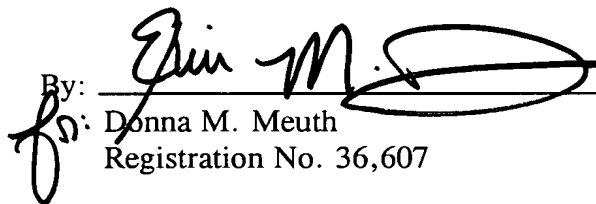
Withdrawal of the rejections of record are respectfully requested and believed to be in order.

Further and favorable action in the form of a Notice of Allowance is respectfully requested. Such action is believed to be in order.

In the event that there are any questions relating to this Amendment, or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at 508-339-3684 concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By:  #51,147
for Donna M. Meuth
Registration No. 36,607

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

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